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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/760,144

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David Y. Kim

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EXAMINER

SONG, MATTHEW J

ART UNIT

PAPER NUMBER

1792

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DELIVERY MODE

04/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/760,144	Applicant(s) KIM ET AL.	
	Examiner MATTHEW J. SONG	Art Unit 1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/27/2007 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 53, 55, and 65-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Carter (US 5,641,681).

Carter et al discloses a method of protein crystallization comprising a device for hanging drop vapor diffusion having a first chamber **13** and a second chamber **14** for containing crystallization solutions (col 7, ln 1-20 and col 8, ln 50-67 and Fig 5). Carter et al also discloses a tube **22** between the first and second chamber. (col 9, ln 1-10 and Fig 5). Carter et al also discloses a plurality of pairs of chambers arranged side-by-side and a protein solution is sealed with a coverslip and a solution of precipitant is sealed in the second chamber (col 7, ln 1-25 and

col 9, ln 1-20 and Fig 5), this reads on a first plurality of solutions in a first plurality of chambers. Carter et al teaches the first chamber is sealed on the top and bottom and a channel **22** connecting the chamber to the external atmosphere, where the “external” atmosphere is the atmosphere of the second chamber which is external to the atmosphere of the first chamber . (Fig 5 and col 9, ln 1-25). Carter et al teaches diffusion of the solution through the tube **22** to achieve supersaturation and crystal growth (col 9, ln 1-20), this reads on removing solvent only through the channels to the external atmosphere and each solution undergoes a phase transition because the liquid solution is turned into a solid crystal.

Referring to claim 55, Carter et al discloses hanging drop vapor diffusion. (col 8, ln 50-67).

Referring to claims 65-67, Carter et al discloses identical solutions with different diffusion rates. (col 9, ln 30-67).

Referring to claim 68, Carter et al discloses noting when crystal growth occurs to determine optimum crystal growth (col 10, ln 10-60).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 54, 56-64 and 69-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter (US 5,641,681) as applied to claims 53, 55, and 65-68 above, and further in view of Forsythe et al (“Vapor diffusion, nucleation rates and the reservoir to crystallization volume ratio” from IDS 12/14/2004).

Carter et al teaches all of the limitations of claim 56, as discussed previously, except the compound in each solution of the first plurality is different prior to removing solvent. Carter et al does teach suitable crystallization conditions are determined by performing hundreds of experiments and protein concentration is a known result effective variable. (col 1, ln 55-67).

In a method of vapor diffusion crystallization, note entire reference, Forsythe et al teaches an experiment where lysosyme (protein) experiments that were conducted at different NaCl concentrations, 4% and 5% NaCl (pg 1603 and Table 2). Forsythe et al also teaches a third tray was set up with all ratios in duplicate wells (pg 1603). Forsythe et al also teaches greater crystal growth in the 5% NaCl solution compared to the 4% NaCl solution for the same reservoir to drop volume ratio (Table 2).

It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Carter et al by conducting experiments for different concentrations of

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solutions, as taught by Forsythe et al to determine the optimum solution concentration for crystal growth. Furthermore, it is known to screen more than 1000 crystallization conditions to find suitable conditions that yield high quality protein crystal, thus it would have been obvious to a person of ordinary skill in the art at the time of the invention to conduct experiments where the concentration is changed while other conditions (i.e. rate) are maintained to determine the effect of concentration on protein yield ('681 col 1, ln 55-67).

Referring to claim 56 and 69, it is known to screen more than 1000 crystallization conditions to find suitable conditions that yield high quality protein crystal, thus it would have been obvious to a person of ordinary skill in the art at the time of the invention to conduct experiments where the concentration is changed while other conditions, including rate, are maintained to determine the effect of concentration on protein yield ('681 col 1, ln 55-67). Also, using an optimized rate determined from previous experiments would have been obvious to a person of ordinary skill in the art.

Referring to claim 54, 61, 70, the combination of Carter and Forsythe et al hanging drop vapor diffusion crystal growth ('681 col 8, ln 50-65). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the combination of Carter and Forsythe et al by carrying out the process until completion, i.e. until only solid remains.

Referring to claim 58 and 73, the combination of Carter and Forsythe et al teaches preparation of individual experiments at increments in 5% steps of each of the precipitant concentration is known in the art of screening crystallization conditions. ('681 col 10, ln 15-20).

Referring to claim 59, the combination of Carter and Forsythe et al teaches crystallization.

Referring to claim 60, the combination of Carter and Forsythe et al teaches screening crystallization conditions. Therefore, using crystallization conditions which were previously successful (concentration) would have been obvious to one of ordinary skill in the art and it is also noted that the prior art recognizes that concentration is a result effective variable, as discussed previously, thus the use of an optimized concentration would have been obvious to a person of ordinary skill in the art.

Referring to claims 62-63, the combination of Carter and Forsythe et al teaches different rates for identical solutions. ('681 col 9, ln 30-67)

Referring to claim 64 and 72, the combination of Carter and Forsythe et al does not teach removal varies by at most 5%. The combination of Carter and Forsythe et al teaches preparation of individual experiments at increments in 5% steps of each of the precipitant conditions (i.e. conditions) and thousands of experiments are known in the art to be performed to screen crystallization conditions. ('681 col 10, ln 15-30 and col 1, ln 55-67). Therefore, small incremental steps, i.e. 5% or less for rate, would have been obvious to a person of ordinary skill in the art to determine the optimal crystallization conditions.

Referring to claim 71, the combination of Carter and Forsythe et al teaches different concentration (Forsythe).

Response to Arguments

6. Applicant's arguments with respect to claims 53-73 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. SONG whose telephone number is (571)272-1468. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Barr can be reached on 571-272-1414. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Matthew J Song
Examiner
Art Unit 1792

MJS
March 30, 2008

/Robert M Kunemund/
Primary Examiner, Art Unit 1792